***In Re National Prescription Opiate Litigation* (MDL No. 2804)**

SUMMARY SHEET OF ISSUES RAISED

Manufacturer Defendants' Reply in Support of Motion For Summary Judgment That Plaintiffs' State-Law Claims Are Preempted And Their Federal Claims Are Precluded (filed August 16, 2019)

A. Preemption of Marketing Claims

Issue 1: Are Plaintiffs correct that they "do not challenge the FDA-approved labeling of any of the Manufacturers' products" (Opp'n at 10; *see also id.* at 12-13)?

Answer to Issue 1: No. Plaintiffs again ignore that the term "labeling" broadly encompasses "representations made in marketing materials." *See Muscogee* R. & R. at 30, ECF No. 1499, *adopted by* Op. and Order at 2, ECF No. 1680; *see also* 21 U.S.C. § 321; *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013). And Plaintiffs *do* seek to hold the Manufacturers liable for marketing their medications for the treatment of chronic, non-cancer pain and for failing to issue dose and duration limitations. *See, e.g.*, Summit TAC ¶ 172; Rosenthal Opp'n Br. at 5[1]; Ex. 2 (Report of David T. Courtwright, Ph.D.) at 54; Ex. 3 (Report of Anna Lembke, M.D.) at 21-63; Ex. 10 (Plaintiffs' Nov. 2, 2018 Amended Responses to First Set of Interrogatories) at 6.

Issue 2: Are Plaintiffs correct that "[t]here can be no preemptive conflict between state law claims and federal law, because federal law did not *require* the Manufacturers to promote their products" (Opp'n at 10-11)?

Answer to Issue 2: No. *See, e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013) ("[A]n actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability."); *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1681 (2019) (Thomas, J., concurring); *In re Darvocet, Darvon, and Propoxyphene Prods. Liability Litig.*, 756 F.3d 917, 925 (6th Cir. 2014).

Issue 3: Are Plaintiffs correct that "the Manufacturers have failed to show that Plaintiffs' fraudulent marketing claims conflict in any way with the regulatory actions taken by the FDA" (Opp'n at 13)?

Answer to Issue 3: No. "[C]lear evidence" exists that the FDA would not have approved the labeling and marketing changes that Plaintiffs demand. *See Merck*, 139 S. Ct. at 1676 (citing *Wyeth v. Levine*, 555 U.S. 555, 571 (2009)). In 2013, the FDA rejected requests to label opioid medications as unsafe for the treatment of chronic, non-cancer pain and to impose maximum dose and duration requirements. *See* Ex. 12 (Sept. 10, 2013 Letter from FDA to PROP) at 5, 6 & n.30, 8, 11-17. The FDA reiterated these findings as recently as May 2019, negating Plaintiffs' theory that the FDA's 2013 findings are no longer valid. *See* Ex. 1 (May 2019 FDA

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[1] All exhibits referenced herein are exhibits to the Declaration of Jonathan L. Stern in Support of Manufacturer Defendants' Motion for Summary Judgment that Plaintiffs' State-Law Claims Are Preempted and Their Federal Claims Are Precluded.

Memorandum) at 9, 10, 12. Indeed, on July 22, 2019, a North Dakota court reaffirmed its holding that similar claims are preempted. *See* Order Denying Pl's. Rule 60(b) Mot. For Relief from Judgment, *N. Dakota v. Purdue Pharma L.P.*, No. 08-2018-CV-01300, 2019 WL 3776653 (N.D. Dist. Ct. July 22, 2019).

B. Preemption of Fraud-On-The-DEA Claims

Issue 4: Are Plaintiffs correct that their state-law claims "do not depend upon the DEA's decision to increase quotas for opioid medications" (Opp'n at 17)?

Answer to Issue 4: No. *Buckman Company v. Plaintiffs' Legal Cmte.*, 531 U.S. 341 (2001) preempts state-law claims for which establishing fraud on a federal agency is a "critical" factor that "would exert an extraneous pull on the scheme established by Congress." *McDaniel v. Upsher-Smith Laboratories, Inc.*, 893 F.3d 941, 948 (6th Cir. 2018) (quoting *Buckman*, 531 U.S. at 353); *see also Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 966 (6th Cir. 2004) ("[S]tate tort remedies requiring proof of fraud committed against [a federal agency] are foreclosed since federal law preempts such claims" (citation omitted)). Plaintiffs allege—and their experts agree—that it would have been "impossible" for the Manufacturers to "achieve their ever-increasing sales ambitions" had they not "fraudulently increase[d] the quotas that governed the manufacture and distribution of their prescription opioids." Summit TAC ¶ 526; Cuyahoga TAC ¶ 526; *see also* Summit TAC ¶¶ 548–553; Cuyahoga TAC ¶¶ 531–536; Ex. 14 (Pls' Dec. 28, 2018 Suppl. Objs. & Resp. to Mfr Defs.' Interrog. Nos. 28/29) at ¶¶ 4, 7, 28, 30, 32, 34. Indeed, the Court found that Plaintiffs' theory of but-for causation depends on showing the Manufacturers "undermin[ed]" the DEA's quotas—a finding that should end any debate here. *See Summit* R. & R. at 26, ECF No. 1025, *adopted by* Op. and Order at 8, ECF No. 1203.

Issue 5: Are Plaintiffs correct that *Buckman*, 531 U.S. 341, does not preempt their state-law claims if they assert that the Manufacturers were able to sell excess opioids because they misled the DEA into increasing quotas?

Answer to Issue 5: No. In fact, Plaintiffs do not dispute that *Buckman* preempts state-law claims that rest upon fraud on a federal agency.

C. Preclusion of Marketing and Fraud-On-The-DEA Claims

Issue 6: Are Plaintiffs correct that their federal claims are not precluded by *Wyeth/Merck* and *Buckman*?

Answer to Issue 6: No. Indeed, Plaintiffs do not dispute that their federal claims are precluded if their state-law claims are preempted. *See* Opp'n at 17. Because their state-law claims are preempted, Plaintiffs' federal claims are similarly precluded.